Patient consent preferences for research uses of information in electronic medical records: interview and survey data

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Abstract

Objectives To assess patients' preferred method of consent for the use of information from electronic medical records for research.
Design Interviews and a structured survey of patients in practices with electronic medical records.
Setting Family practices in southern Ontario, Canada.
Participants 123 patients: 17 were interviewed and 106 completed a survey.
Main outcome measures Patients' opinions and concerns on use of information from their medical records for research and their preferences for method of consent.
Results Most interviewees were willing to allow the use of their information for research purposes, although the majority preferred that consent was sought first. The seeking of consent was considered an important element of respect for the individual. Most interviewees made little distinction between identifiable and anonymised data. Research sponsored by private insurance firms generated the greatest concern, and research sponsored by foundation the least. Sponsorship by drug companies evoked negative responses during interview and positive responses in the survey.
Conclusions Patients are willing to allow information from their medical records to be used for research, but most prefer to be asked for consent either verbally or in writing.

Introduction

Researchers and policy makers studying quality of medical care have traditionally used datasets to study the effectiveness of treatments. Recently, however, researchers have turned to electronic medical records, which contain more clinically relevant information. In some cases, such as registries, the clinical datasets are designed with a view to conducting research in the "usual practice" environment of family physician visits and specialist consultations. Although electronic medical records offer the potential to investigate strategies to improve quality of care in practice, this area of research increasingly blurs the boundary between patient care and research.[1]

To minimise selection bias, observational studies require a high participation rate. Obtaining individual informed consent poses major logistical challenges and threatens to reduce generalisability of findings. In response, many researchers have sought exemption from the consent requirements for use of such information for research. Yet, a recurring theme in studies of patients' perceptions of the use of electronic medical records was concern over confidentiality.[2] We assessed concerns over the use of information from electronic medical records for research and preferences for consent of patients whose doctors were enrolled in a southern Ontario project to improve prescribing through the use of electronic medical records, called the COMPETE study (Computerization of Medical Practices for the Enhancement of Therapeutic Effectiveness).

Participants and methods

Our study comprised two steps: semistructured interviews with patients of doctors in the COMPETE study and a structured fixed response survey of patients registered with the doctors in our study. This study received separate ethics approval from the COMPETE study.

Semistructured interviews

We interviewed 18 patients (seven men, 11 women). One male participant later withdrew from the study, leaving 17 patients: five responded to notices in their doctor's practice, and 12 were identified by their doctor as being interested in the use of data for research purposes. The individual who withdrew from the study had responded to a notice in his doctor's practice. The interviews explored preferences for being approached (post, brochure in waiting room, discussion with doctor, etc), the amount of detail to be provided about the research, the method of consent (positive or negative option, verbal or written), and conditions around consent for any future uses of the information. We also explored the influence of different sources of funding on willingness to participate. Although the interviews were structured, patients' responses were open ended and there was opportunity for concerns to be raised. The interviews were audiotaped, transcribed, and coded independently by two reviewers. Results were

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organised with QSR NUD*IST (version 4.0; Qualitative Solutions and Research, Australia).

Fixed response survey

Based on the interviews, we developed a fixed response survey to examine preferences for methods of consent in a representative sample of patients. The research coordinator spent half a day in each of 11 practices, approaching consecutive patients. Eligible patients were over 18 years of age, spoke sufficient English to respond to the survey, and were not cognitively impaired.

The survey specified that information gleaned from the records would be stripped of direct identifiers (name, address, telephone number, health card number) before being transferred from the doctor's computer to the research computer, without anyone reading the records. Patients were asked about the amount of detail they would want to know about the research, their preferred method of being informed, the length of time that consent should be considered valid, the impact of sponsorship, and personal characteristics. The surveys were completed by the patients in the waiting room and returned to the research coordinator.

Statistical analysis

We used SPSS (version 9.0) for general descriptive statistics. We applied the Kruskal-Wallis test of identical distribution of responses to observed differences between the sexes for the amount of detail patients wanted to know about the research. We applied the Wilcoxon signed rank test (StatXact; version 4; CYTEL Software, Cambridge, MA) to observed differences in level of concern about sponsorship.

Results

Interviews

Qualitative analysis yielded three major themes: balancing preferences for consent with pressures on time in the consultation, being treated with respect, and balancing the benefits and concerns related to research.

Patients did not want the obtaining of consent to detract from the reason for their appointment. They expected their health, not research, to be the focus of the consultation. However, they believed that they should be informed of any research that used information from their medical records. Most also thought that obtaining consent before use of that information would lead to less confusion and uncertainty:

I think that number 3 [providing written consent] would be the one that would probably give the most protection to all people involved. Because if you do one of the other things, information is used or given out or whatever and then I find out about it later and I decide to raise questions, then how can my physician explain himself. He's done this without my consent. But if there is a consent form on file, then we're both bound by that. And that would seem to me, if you're going to formalise it, the best way to do it. Patient 6

Most patients were unaware that information on their health was currently being used for research purposes, despite a notice to that effect in the waiting room. A common sentiment was that it was a sign of respect that they be asked for permission first:

I think you need to give conscious consent to having any data, any personal data used, whether you are identified or not. That's certainly a right. That's your information, it's your medical history. Whether it's identified or not, you should control it. Patient 14

Patients generally expressed great trust in their doctor's judgment. This trust was often associated with less concern for obtaining detailed information about the use of personal information for research:

If you trust the doctor, I don't think it would worry me how much [data] you needed, and I do trust the doctor. Patient 15

This preference for consent extended to any new uses of the information in the future:

I would want to be able to consent to the use of the information for the new study, because … if it's a particular area that I worried about or have some reason to be concerned about, then I would want to know. Patient 6

Most patients thought about research in broad, general terms. For most, the interviews marked their first experience with medical research. The patients generally were positive about participating in research, noting that they wanted to help others:

If I could help other people and they need help down the road then I'm more than happy to do what I can. Patient 16

I think the medical research is going to be of general benefit to the general population and if my records can help; I think personally I would be quite willing to participate in any medical study that is of general benefit to the population. I just feel it is worth while to participate in these studies. Patient 4

Patients were also asked their concerns on five sources of research funding (drug companies, software companies, insurance companies, government, and foundations). Strong concerns were voiced about funding by drug and insurance companies. Patients were wary of drug companies funding research in an effort to promote their product and of insurance companies withholding coverage for patients:

I would be even more concerned about a pharmaceutical firm because again I don't believe for a minute that these people put money into these projects from much of an altruistic vantage point. They're looking for a way to sell their product. So I would be concerned about those kind of companies putting money in. Money is money, but you have to look at the strings that may be attached. Patient 6

It would have to be done for the right reasons and not just to enhance their, that company's product. Patient 7

Insurance companies have a nasty habit of immediately using it as way of, you know, somebody not getting insured, especially if they insist on some of the information. Which presumably if they helped to pay for the study, they would. I think it's a little dicey. I know I won't be happy with that. Patient 15

Patients were generally opposed to the idea of a researcher selling personal data to another researcher for a profit. However, they did consider it reasonable to charge to cover costs—for example, preparation time—or if those funds were reinvested in research.

I guess the issue for me would be what would they do with the money that they got from the sale of that data. If it was to make a profit, it would probably bother me. If they used it to fund research or put it back into the development of medications of some other sort, then it wouldn't bother me. Patient 9

Table 1 Characteristics of survey respondents

Characteristic	No (%) of men (n=33)	No (%) of women (n=73)*	Total
Age (years):			
18-34	6 (18)	13 (18)	19/105 (18)
35-44	7 (21)	19 (26)	26/105 (25)
45-64	9 (27)	16 (22)	25/105 (24)
≥65	11 (33)	24 (33)	35/105 (33)
No of visits to family doctor in past year:			
0-1	8 (24)	7 (10)	15/104 (14)
2-5	13 (39)	39 (55)	52/104 (50)
6-10	12 (36)	25 (35)	37/104 (36)
Prior participation in research study:			
Yes	2 (6)	15 (21)	17/106 (16)
No	27 (82)	54 (74)	81/106 (76)
Not sure	4 (12)	4 (6)	8/106 (8)

*Denominators vary.

Naivety of interviewees

Most patients had given little or no prior thought about the use of their personal information for anything other than their own health care. As the interviews progressed, the patients often formulated and revised their opinions on how much information they would want on the research, how they would like to be informed, and future uses of the information.

Fixed response survey

Overall, 106 of 117 patients (91%) completed the survey: six (5%) were excluded due to lack of fluency in English, deafness, or cognitive impairment, and five (4%) were not interested in participating. The survey took five minutes. Table 1 lists the characteristics of the respondents.

Opt-in or opt-out preference for consent

Twenty eight patients (26%) were satisfied with being notified passively about the use of their personal information for research purposes, with the option to opt out at any time. The remaining 78 patients (74%) wanted the opportunity to provide consent first. Preference for verbal and written consent was equal.

Level of detail

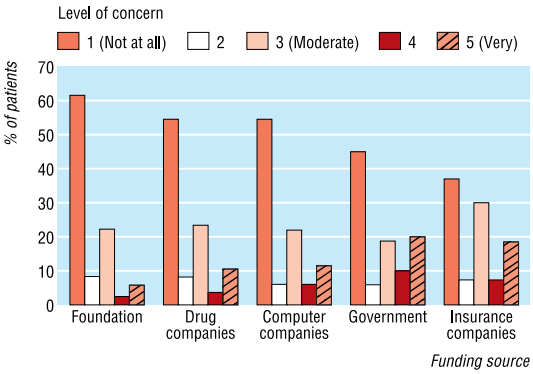
Table 2 shows the level of detail patients wanted about research that used their data. The original four categories were collapsed into three to reflect a preference for minimal, limited, and detailed information. Sixty patients (57%) wanted to know specific information: name of study, goals, benefits to others, and funding source. Women requested more details than men (62% and 46%; Kruskal-Wallis exact test P=0.052); although not significant, the difference in point estimates is large.

Time limit

Thirty two patients (31%) needed no time limit for consent. Fifty two patients (49%) thought that consent should be valid for the duration of the study, and 21 (20%) preferred an annual review.

Source of funding

Fifty four patients (51%) expressed moderate to high concern over their doctor participating in research funded by insurance companies, and 46 (43%) expressed similar concern for government sponsorship (figure). The difference in level of concern was not significant. Funding by foundations evoked the least concern, and funding by the drug industry evoked relatively low concern. The difference in response between these two sources was not significant.



Pair wise comparisons for level of concern using Wilcoxon signed rank test (exact inference, two sided P value)

	Drug companies	Computer companies	Government	Insurance companies
Foundation	0.072	0.037	0.000	0.000
Drug companies		0.793	0.002	0.000
Computer companies			0.022	0.003
Government				0.351

Level of concern over sources of funding for research

Discussion

Patients are willing to support and participate in research but want to be consulted first on the use of information from their medical records. They are also concerned about secondary uses of their data, particularly for marketing and insurance purposes. These messages are consistent with other surveys in recent years in Canada, showing that the public values both use of their information for research and privacy.[3 4] Also, the lack of distinction between identifiable and anonymised information was consistent with a survey in Australia.[5]

In Canada, federal and provincial data protection laws apply to personal information only, but federal law is unclear in its definition, and there are inconsistencies across provincial legislation.[6] The Canadian

Table 2 Amount of detail men and women want to know about study. Values are numbers (percentages) of patients

Amount of detail	Men*	Women*	Overall
Minimal information	n=33	n=73	n=106
Only want to know that information is being used for research study	9 (27)	8 (11)	17 (16)
Limited information			
Want to know study is being done using information and that more details can be given if asked for or want to know general type of research being done but no details	9 (27)	20 (27)	29 (27)
Detailed information	n=15	n=45	n=60
Want to know:			
Name of study	13 (87)	36 (80)	49 (82)
Goals of study	12 (80)	37 (82)	49 (82)
How patient or others will benefit from study	10 (67)	39 (87)	49 (82)
Who is paying for study	8 (53)	26 (58)	34 (57)
What happens to information after it is collected	11 (73)	38 (84)	49 (82)
Other	4 (27)	3 (7)	7 (12)

* Distribution by sex identical by Kruskal-Wallis exact test.

Determinants of impracticability for obtaining consent for research

- Size of population being researched
- Difficulty of contacting participants, either directly or indirectly
- Resultant risk of introducing bias into the research
- Risk of breaching privacy or inflicting psychological, social, or other harm by contacting the individual
- Undue hardship imposed on organisation when additional financial, material, human, or other resources are required
- It has also been recommended that determination of impracticability be made by a duly constituted research ethics board[8]

Institutes of Health Research defines personal information as information that can identify, either directly or indirectly, a specific individual, can be manipulated by a reasonably foreseeable method to identify a specific individual, or can be linked with other accessible information by a reasonably foreseeable method to identify a specific individual.[7]

We removed all direct identifiers before transferring information from the electronic medical records. It was, however, still possible to indirectly identify an individual through the variables that remained. When the COMPETE study began, the responsible research ethics board did not require individual patient consent for use of data for research, as the focus of the research was on doctors' prescribing behaviour. This decision predated the Canadian Institutes of Health Research recommendation, as it applies to the federal data protection law.

Canadian federal and provincial laws generally allow for exemptions from consent for research purposes when, among other conditions, the research cannot be achieved without using personal information and it is impracticable to obtain consent. Existing legislation does not interpret impracticability. The Canadian Institutes of Health Research considers several determinants of impracticability (box).[7]

These recommendations apply chiefly to existing datasets. It is more difficult to argue the impracticability of obtaining consent when designing, prospectively, a clinical information system where ongoing research is intended. How, then, should consent be sought? Doctors have insufficient time to obtain consent during consultations. This was recognised by the patients in our study. Doctors also feel uncomfortable with obtaining consent.[9] They are probably not the most appropriate people to obtain consent anyway because they are ongoing care providers and have a trust relationship with their patients.

It makes more sense to engage the public more generally in the use of personal information for research purposes. Indeed, good dialogue has been lacking between researchers and the public on the conditions under which use of such information may be permitted for health research without individual consent.

One approach would be to develop an "information directive," with patients identifying in advance the purposes for which information may be used.[10 11] Such a directive would not be able to provide the specifics of each use. Nevertheless, patients could be advised of potential uses and have the opportunity to consent for use of data at different levels of detail, depending on the application. A key challenge is providing the appropriate environment to allow truly informed choices.

Study limitations

To determine the breadth of patients' concerns, we sought out patients who may have had concerns over computerisation of their doctor's practice. However, most who came forward had given little thought to the topic. Responses shifted during the interview, and ambiguities persisted. Most patients had difficulty articulating their thoughts, so it was often problematic to discern their sources of anxiety. Our findings should therefore be interpreted with caution.

The level of concern over use of the data varied with type of sponsorship. The findings in the fixed response survey were inconsistent with those of the interviews. Several interviewees indicated great concern if a drug company was the potential sponsor, whereas survey respondents' trust in research sponsored by drug companies was second only to foundations. Much of this inconsistency may be attributed to sentinel events in the media. At the time of the interviews there was prominent coverage of a dispute between a doctor and a pharmaceutical firm over publication of adverse findings of one of its products. By the time of the fixed response survey, a series of television advertisements sponsored by the Research-based Pharmaceutical Manufacturers' Association had been running for several weeks, promoting the health benefits of pharmaceutical innovation generally.

Although our fixed response survey had internal validity, the doctors who participated in the COMPETE study tended to be younger than average, and a greater proportion of those whose patients we studied were in singlehanded practice. The generalisability of our findings to other practices that keep electronic medical records is unknown.

Fixed response surveys have a limited ability to capture the tension between privacy and the potential benefits of research. Interviews and surveys are subject

What is already known on this topic

Legislation is being introduced worldwide to restrict the circumstances under which personal information may be used for secondary purposes without consent

Little empirical information exists about patients' concerns over privacy and preferences for consent for use of such information for research

What this study adds

Patients are willing to allow personal information to be used for research purposes but want to be actively consulted first

Patients make little distinction between identifiable and non-identifiable information

Most patients prefer a time limit for their consent

to framing bias and tend to address this tension in a superficial fashion, if at all. We therefore attempted to frame our questions in a neutral way. It may have been helpful to provide one or more case studies for patients to respond to, or to engage the public more widely through, for example, a citizens' jury or deliberative polling.[12 13]

Conclusions

Patients are willing to allow their information to be used for research purposes, but most want to be consulted first. Obtaining individual consent for registries and research studies using medical records presents logistical challenges that call for new approaches to consent, taking into account the varying needs of the public and the evolving uses of personal information in a broader context.

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